

**GOLDMAN ISMAIL TOMASELLI BRENNAN & BAUM LLP**

WRITER'S DIRECT DIAL  
312-881-5947  
scCook@goldmanismail.com

August 9, 2013

**VIA FAX**

The Honorable Cathy Seibel  
United States District Judge  
The Hon. Charles L. Brieant Jr. Federal Building and U.S. Courthouse  
300 Quarropas St.  
White Plains, NY 10601-4150

**Re: *In re: Mirena IUD Products Liability Litigation*, 13-MD-2434, 13-MC-2434  
Update on Plaintiff Fact Sheet, Defense Fact Sheet and ESI Protocol**

Dear Judge Seibel:

As discussed in my letter to the Court of August 7, 2013, the parties have met and conferred by phone, email and in person about the Plaintiff Fact Sheet, Defense Fact Sheet, and ESI and document production protocol. The parties address the status of these issues below.

**Plaintiff Fact Sheet**

The parties have met and conferred on the Plaintiff Fact Sheet and a related Case Management Order. There are no outstanding issues for the Court to resolve.

Because the parties have only reached final agreements on these documents within the past few hours, the parties have not had a chance to carefully review these drafts to ensure that they reflect the parties' agreements. As such, the parties will submit the drafts to the Court on Monday.

**Defense Fact Sheet**

The parties have met and conferred on a Defense Fact Sheet and a related Case Management Order. The parties reached agreement on a proposed Case Management Order related to the Defense Fact Sheet. Again, because the parties have only reached a final agreement on this document within the past few hours, the parties have not had a chance to carefully review the draft to ensure that it reflects the parties' agreement. As such, the parties will submit a draft to the Court on Monday.

The draft Defense Fact Sheet is attached with the remaining areas of dispute highlighted, which are also outlined in the below chart.

**GOLDMAN ISMAIL TOMASELLI BRENNAN & BAUM LLP**

The Honorable Cathy Seibel

-Page 2-

August 9, 2013

<b>Issue</b>	<b>Plaintiffs' Position</b>	<b>Defendant's Position</b>
Scope of discovery of Bayer sales contacts with, communications with, promotional items provided to, consulting payments to, and prescribing practices of physicians	<p>Plaintiffs seek information relating to the prescribing physician, the inserting physician, and a follow-up doctor (4-6 week follow-up or yearly visit or next visit) that the Plaintiff will identify at time of submitting PFS.</p> <p>Plaintiffs view the follow-up physician as directly relevant to determining proper placement of the Mirena at insertion. Inevitably, the follow-up physician will be deposed on this exact issue so his contacts with Defendant are clearly discoverable and relevant.</p>	<p>This information is only relevant to the prescribing physician under the learned intermediary doctrine. Consistent with how this issue has been handled in most if not all pharmaceutical MDLs, Bayer offered to provide this information for the physician who prescribed and/or inserted the Plaintiff's Mirena. Physicians who later examined Plaintiff did not perform a risk/benefit analysis and this information is not relevant. In addition, providing this information for each Plaintiff would be unduly burdensome to Defendant.</p>
Bayer sales calls for products other than Mirena	Plaintiffs requested the total number of non-Mirena sales calls made by Defendant's women's healthcare sales representatives each year from the first Mirena sales call to the present.	<p>Defendant does not believe sales calls related solely to Defendant's other products are relevant to any issue in the litigation.</p> <p>As a compromise, Defendant offered to give the annual number of sales calls on all products by each sales representatives within the 3 years prior to Plaintiff's insertion of the Mirena.</p>

**GOLDMAN ISMAIL TOMASELLI BRENNAN & BAUM LLP**

The Honorable Cathy Seibel

-Page 3-

August 9, 2013

**ESI and Document Production Protocol**

The parties continue to meet and confer on a Case Management Order addressing the preservation of documents and the format of document production and privilege logs. It is too early to identify what issues remain in dispute. The parties will be prepared to address any remaining issues at the conference on August 14.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Shayna S. Cook', written in a cursive style.

Shayna S. Cook  
*Lead Counsel for Defendant*  
*Bayer HealthCare Pharmaceuticals Inc.*

CC (via email):

Counsel for Plaintiffs Diogenes P. Kekatos, Fred Thompson, James R. Ronca, Matthew McCauley; Counsel for Bayer James Shepherd, and William Harrington

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**MIRENA®**

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***UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK***

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***IN RE:***

**13-MD-2434 (CS)(LMS)**

***MIRENA IUD PRODUCTS LIABILITY LITIGATION***

***THIS DOCUMENT RELATES TO:***

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**MIRENA DEFENDANT'S FACT SHEET**

For each case, the Defendant must complete this Defendant's Fact Sheet ("DFS") and identify or provide documents and/or data relating to each Plaintiff, responsive to the questions set forth below to the best of Defendant's knowledge. In completing this DFS, you are under oath and must provide information that is true and correct to the best of your knowledge at the time you complete this DFS. If you cannot recall all of the details requested, please provide as much information as you can. The DFS must be supplemented or revised upon receiving any information making any answer incorrect or incomplete.

**You may attach as many documents (as defined below) as necessary to fully answer these questions.**

As used herein, the term "Documents" shall include, information stored, maintained or available to Defendant, including without limitation, any written, printed, typed, photostatic, photographed, recorded, computer generated, computer-stored, or otherwise maintained or reproduced communication or representation, any data compilation in any form, whether comprised of letters, words, numbers, pictures, sounds, bytes, emails, electronic signals or impulses, electronic data, active files, deleted files, file fragments, or any combination thereof including, without limitation, all memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, projections, estimates, working papers, accounts, analytical records, reports and/or summaries of investigations, opinions or reports of consultants or experts not retained for purposes of litigation, opinions or reports of accountants, other reports, trade letters, press releases, comparisons, books, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, forecasts, drawings, diagrams, instructions, minutes of meetings or communications of any type, including inter- and intra-office communications, questionnaires, surveys, charts, graphs, photographs,

films, discs, data cells, drums, printouts, all other compiled data which can be obtained, documents maintained on, stored in or generated on any electronic transfer or storage system, any primary versions, drafts or revisions of any of the foregoing, and shall include all non-identical copies and drafts of any of the foregoing now in the possession, custody or control of Defendant. Defendant are not required to identify or produce any pleading filed in litigation relating to Mirena<sup>®</sup> (“Mirena”) or medical records produced in Plaintiff’s individual case.

As used herein, the terms “you,” “your” or “yours” means Defendant (as identified in the Agreed Order Regarding Property Party Defendant) and any officers, agents, employees, representatives or others acting on its behalf.

As used herein, the phrase “provided” means sold, distributed, shipped, delivered or otherwise placed into the stream of commerce.

As used herein, the term “communication” and/or “correspondence” shall mean and refer to any oral, written, spoken or electronic transmission of information, including, without limitation, meetings, discussions, conversations, telephone calls, memoranda, letters, e-mails, voice recordings, postings, instructions, conferences, or seminars or any other exchange of information between Defendant or between you and any other person or entity.

Nothing in this DFS shall be construed contrary to the requirements of the Preservation Order, or any other Order, in this action.

As used herein, the phrase “Specified Health Care Provider(s)” means each of Plaintiff’s medical providers who prescribed and/or inserted Plaintiff’s Mirena(s) **[PLAINTIFF’S PROPOSAL: and a follow-up doctor (4-6 week follow-up or yearly visit or next visit)]** as identified with particularity in the Plaintiff Fact Sheet (“PFS”).

As used herein, the phrase “Promotional Items” means any and all promotion items, marketing devices, freebies, merchandise, handouts, meals, or any other items related to Mirena<sup>®</sup> including but not limited to physical items marked with the Mirena<sup>®</sup> trademark such as anatomical models, notepads, post-it-notes, pens, flashlights, other day-to-day office supplies of any type, models for patient demonstration, diagnostic tools and aids, medical assessment and dosage calculators, pharmacy and pharmacist tools, patient compliance tools, custom medical calculators and software, branded apparel (such as but not limited to shirts, hats, etc), leather portfolios, prescription pads, picture frames, letter openers, clipboards, water bottles, coffee mugs/cups, pocket/pen lights, key chains, badge-holders, bags, travel accessories, other “freebies” provided to Implanting/Prescribing Health Care Providers (this list is not meant to be exhaustive). “Promotional Items” shall mean and include any and all cross-promotional materials related to Mirena<sup>®</sup> jointly with other products or advertising campaigns.

As used herein, the term “identify” or “identity” with respect to persons, means to give, to the extent known, the person’s full name, and as to former employees or third –parties, their present or last known address.

As used herein, the term “person” means natural person, as well as corporate and/or

governmental entity.

As used herein, the terms “relating to,” “relate to,” “referring to,” “refer to,” “reflecting,” “reflect,” “concerning,” or “concern” shall mean evidencing, regarding, concerning, discussing, embodying, describing, summarizing, containing, constituting, showing, mentioning, reflecting, pertaining to, dealing with, relating to, referring to in any way or manner, or in any way logically or factually, connecting with the matter described in that paragraph of these demands, including documents attached to or used in the preparation of or concerning the preparation of the documents.

Unless otherwise indicated, the “relevant period” for the information sought is January 1, 2000 to the present.

Nothing herein prohibits Defendant from redacting any materials or information that constitute trade secrets, provided these documents are listed on the redaction log.

If a claim of privilege is made, a privilege log shall be provided to Plaintiffs’ counsel pursuant to sections \_\_\_\_ of the Preservation and Production Protocol agreed to and entered in this MDL litigation.

**I. CASE INFORMATION**

This DFS pertains to the following case:

Case caption: \_\_\_\_\_

Civil Action No.: \_\_\_\_\_

Court in which action was originally filed: \_\_\_\_\_

Date that this DFS was completed: \_\_\_\_\_

Name and address of all persons who provided information responsive to the questions posed in this DFS:

A: \_\_\_\_\_  
(Name)  
\_\_\_\_\_  
(Address)  
\_\_\_\_\_  
(Phone Number)

B: \_\_\_\_\_  
(Name)

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 (Address)

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 (Phone Number)

## II. CONTACTS WITH HEALTH CARE PROVIDERS

For each Specified Health Care Provider identified in the PFS, please state the following:

### A. Dear Doctor Letters:

1. Please identify and provide information below for each “Dear Doctor” or “Dear Health Care Provider” letter that you contend was actually sent to the Plaintiff’s Specified Health Care Provider concerning Mirena® from 2000 through the date of removal.

Sender (Name and Address)	Letter or Document Date	Recipient (Name and Address)	Bates Number of Supporting Documentation

2. Please identify the person or persons who provided information responsive to Section II or any of its subparts.

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**B. Physician's Information Request**

1. If any of the Specified Health Care Provider(s) identified in the PFS has ever contacted Defendant about Mirena, provide the following from 2000 through the date of removal:

Name and Address of Person Making Contact	Date	Name and Address of Recipient	Response Sent (Y/N)	Type of Contact (PIR, call, etc.)

2. For each contact in which a response was sent as indicated by a "Yes" above, please identify the following:

Original Contact Date	Format of Response (Letter or Otherwise)	Date Response Sent	Response Sender (Name and Address)	Response Recipient (Name and Address)	Bates Number of Supporting Documentation

**C. Sales Representative Contacts**

1. For each Specified Health Care Provider identified in the PFS, please produce or identify all contacts and communications between the Implanting/Prescribing Health Care Provider and Defendant's Sales Representatives that relate to Mirena® from 2000 through the date of removal.



<b>Name of Plaintiff's Specified Health Care Provider</b>	<b>Name and, if no longer employed by defendant, last known address and telephone number of Defendant's Sales Representative</b>	<b>Current employment status of Sales Representative</b>	<b>Date Range of Contacts</b>

2. For each Sales Representative or detail person that had contact with each Specified Health Care Provider(s) listed in the PFS regarding Mirena from 2000 through the date of removal please provide the following information:

<b>Plaintiff's Specified Health Care Provider</b>	<b>Name of Sales Rep / Detail Person</b>	<b>Territory (ies) Covered</b>	<b>Date of Hire / Date Last Employed</b>	<b>Supervising District Manager(s) and, if no longer employed by defendant, last known address and telephone number</b>	<b>Supervising Field Sales Director current (or last known) and, if no longer employed by defendant, last known address and telephone number</b>

3. For each Specified Health Care Provider, please state whether Defendant or its representatives ever provided him/her Mirena® samples. If the answer is “yes,” please state from 2000 through the date of removal:

- (a) The number of samples provided;
  - (b) The dates that they were shipped and/or provided;
  - (c) The lot numbers for the samples provided on each date identified;
  - (d) The identity of the person or persons who provided the samples;
  - (e) The identity of the person or persons who received the samples;
4. For each Specified Health Care Provider, please state whether Defendant or its representatives provided him/her with “Promotional Items” from 2000 through the date of removal (if available, a physical sample of each Promotional Item will be produced to Plaintiffs’ Lead Counsel). If the answer is “yes,” please state:
- (a) A description of each Promotional Item provided;
  - (b) The dates that each type of Promotional Item was delivered, shipped and/ or provided;
  - (c) The total quantity of each such Promotional Item was delivered, shipped and/or provided;
  - (d) The identity of the person or persons who provided the Promotional Item;
  - (e) The identity of the person or persons who received the Promotional Item and their title or job description; and
  - (f) The fair market value of each such Promotional Item.
5. For each Specified Health Care Provider, please produce any data or documents that identify whether Defendant’s sales representatives provided him/her with any type of documentation (including published studies or journal articles) relating in any way to the safety, efficacy, benefits, risks or on- or off-label use of Mirena® from 2000 through the date of removal, including, to the extent available:
- (a) A description of each document provided;
  - (b) The dates that the document was mailed and/or provided;

- (c) The identity of the person or persons who provided the documentation;
- (d) The identity of the person or persons to whom the documentation was provided; and
- (e) A copy of any cover letters sent to Plaintiff's Implanting/Prescribing Physician with the material.

6. For each Specified Health Care Provider, please state the number of non-Mirena sales calls made by Defendant's women's healthcare sales representatives during each year [PLAINTIFFS' POSITION: FROM THE FIRST MIRENA SALES CALL TO THE PRESENT] [DEFENDANT'S POSITION: WITHIN THE THREE YEARS PRIOR TO PLAINTIFF'S MIRENA INSERTION]

### **III. CONSULTING WITH PLAINTIFF'S IMPLANTING/PRESCRIBING HEALTH CARE PROVIDER**

- A. If you have retained any of the Specified Health Care Provider(s) listed in the PFS as a Mirena "thought leader," "Key Opinion Leader", a member of a "speaker's bureau", a "clinical investigator", a "consultant" or in any other capacity, from 2000 through the date of removal please provide the following information:

<b>Name of Plaintiff's Specified Health Care Provider consulted or retained by Defendant</b>	<b>Date(s) he or she was consulted or retained</b>	<b>Records of documents related to the consultation/retention role provided to the Specified Health Care Provider by Defendant</b>

- B. For each Specified Health Care Provider identified in the PFS (regardless of whether included in Section III(A) above or not), please state how much money you have paid to them from 2000 through the date of removal, whether for expenses, honoraria, fees, or any other payment, for each calendar year, and produce the 1099s or, if unavailable, other documents or data sufficient to evidence such payments.
- C. For each of the Implanting/Prescribing Health Care Providers identified in Section III(B) above, please identify or provide all documentation detailing the services for which the Specified Health Care Provider was paid from 2000 through the date of removal including but not limited to consulting agreements and contracts.
- D. For each Specified Health Care Provider(s) identified in the PFS, please state whether they attended any Defendant-sponsored luncheons, dinners, CME, conferences or events ("Programs") relating to Mirena® from 2000 through the date of removal. If your answer is "Yes," please state:

<b>Identity of the Specified Health Care Provider</b>	<b>Title, location and date of the Program attended</b>	<b>Topic of the Program</b>	<b>All speakers at the Program</b>	<b>Please provide or identify the agenda/brochure for the Program</b>

- E. Please identify the person or persons who provided information responsive to Section III or any of its subparts, giving their name and, address, and telephone number indicating whether said person is currently an employee of Defendants and/or any of its subsidiaries and the dates of employment.
- F. If available, please identify the person or persons or entity or entities that authored, maintained, and/or disseminated, the documents responsive to Section III.A, giving their name, address, telephone number indicating whether said

person is currently an employee of Defendants and/or any of its subsidiaries or contractors or vendor and the dates of employment.

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**IV. PLAINTIFF'S SPECIFIED HEALTH CARE PROVIDER'S  
IMPLANTING/PRESCRIBING PRACTICES**

For each Specified Health Care Provider identified in the PFS please state and produce the following:

- A. Do you have or have you had access to any database or information which purports to track the dispensing/prescribing practices of any Implanting/Prescribing Health Care Providers listed in the PFS with respect to Mirena® from 2000 through the date of removal.

\_\_\_\_\_ Yes                      \_\_\_\_\_ No

If your answer is "yes", please produce or identify the database or document that captures that information and the name of the department, division, contractor, vendor or other entity that authored or maintained the database or document that capture the information:

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- B. Please identify the person or persons who provided information responsive to Section IV or any of its subparts.

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**V. PLAINTIFF'S MEDICAL CONDITION**

- A. Other than in connection with any adverse event report, have you initiated contact with any of Plaintiff's physicians concerning Plaintiff's injuries?

\_\_\_\_\_ Yes                      \_\_\_\_\_ No

- B. Other than in connection with any adverse event report, have you been contacted by Plaintiff, any of her physicians, or anyone on behalf of Plaintiff concerning Plaintiff (other than counsel for Plaintiff)?

\_\_\_\_\_ Yes

\_\_\_\_\_ No

- C. If your answer to A or B above is “Yes”, please state the name, address and telephone number of these individuals:

Name	Address	Phone

- D. Please produce any non-privileged documents that reflect any communication between Plaintiff, any of her physicians, or anyone on behalf of Plaintiff (other than counsel for Plaintiff) and you concerning Plaintiff.
- E. Please produce a copy of any MedWatch form and any other adverse event reporting document, form, line item listing or other such information whether internal or not, that refers or relates to Plaintiff, including back-up documentation concerning Plaintiff and any evaluation or investigation you did concerning the Plaintiff.
- F. If you cannot identify or provide a Med Watch form or other adverse event reporting documentation for plaintiff, please provide an explanation.
- G. Please identify the person or persons who provided information responsive to Section V or any of its subparts.

\_\_\_\_\_

\_\_\_\_\_

## VI. **ADVERTISING**

- A. Aside from national advertising (i.e., advertising buys that were not directed in any way to specific regions), did you advertise Mirena® in the Media Market in which Plaintiff resided at, or within three (3) years preceding the time she had the Mirena® implanted?

\_\_\_\_\_Yes

\_\_\_\_\_No

If your answer is “Yes,” please provide the following information:

<b>Identity of the Advertisement</b>	<b>Nature of media (print or television)</b>	<b>Identify the media outlet</b>	<b>Dates that advertisements ran</b>

*Please provide or identify true and accurate copies of any advertisement identified above.*

- B. Aside from national advertising, did you advertise Mirena® in the Media Market of any of the Implanting/Prescribing Health Care Providers’ office locations listed on the PFS at, or within three (3) years of, the time that Plaintiff’s Mirena® was implanted?

\_\_\_\_\_Yes

\_\_\_\_\_No

If your answer is “Yes,” please provide the following information:

<b>Identity of the Advertisement</b>	<b>Nature of media (print or television)</b>	<b>Identify the media outlet</b>	<b>Dates that advertisements ran; Prescriber/Dispenser on PFS within 100 miles</b>

*Please provide or identify true and accurate copies of any advertisement identified above.*

- C. Was the Plaintiff registered with any program owned, operated or controlled by Defendant whereby Plaintiff received electronic communications concerning Mirena®?

\_\_\_\_\_ Yes

\_\_\_\_\_ No

If your answer is "Yes", identify or produce documents describing such program and reflecting any communications with the Plaintiff.

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### **VIII. DOCUMENTS**

To the extent you have not already done so, please produce a copy of all documents and things in your possession, custody and control that fall into the categories listed below:

1. Any document sent to or received from any of Plaintiff's Specified Health Care Provider(s) relating to Mirena, subject to the limitations and exceptions described in this DFS.
2. Any document reflecting any actual communication between you and Plaintiff's Specified Health Care Provider(s) concerning the topics identified in Section II.B, subject to the limitations and exceptions described in this DFS.
3. Any documents reflecting any contacts or actual communications between you and any of Plaintiff's Specified Health Care Provider(s) regarding Mirena, subject to the limitations and exceptions described in this DFS.
4. Any document which reflects or purports to describe the Implanting/Prescribing practices of any of Plaintiff's Implanting/Prescribing Health Care Providers relating to Mirena, subject to the approval or agreement of the owner of the prescribing data to release the data.
5. Any and all documentation relating to your retention and/or compensation of any of Plaintiff's Specified Health Care Provider(s) as a Mirena "key opinion leader," "thought leader," member of a "speaker's bureau," "clinical investigator," or "consultant."
6. Any and all documents requested or referred to in Sections I-VII, above.



**DECLARATION**

I am authorized to make this Declaration on behalf of Defendant. The information provided in the foregoing Defendant Fact Sheet has been compiled by employees and legal counsel for Defendant. Although I do not have personal knowledge of all of the information set forth therein, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, understanding, and belief formed after due diligence and reasonable inquiry.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Date